

REMARKS

Claims 1-21 are pending. Claims 1, 4 and 8 have been amended to correct typographical errors. No new matter has been added.

Rejection under 35 USC 112

The Official Action rejected claim 4 under 35 USC 112. As amended, claim 4 recites the correct Markush language.

Rejection under 35 USC 103(a)

The Official Action rejected claims 1-21 under 35 USC 103(a) as unpatentable over US 5,855,590 (Svensson et al.). The Official Action states that “the claims differ over Svensson in reciting a water content below about 1%. However, Svensson recites that the water content of the excipients and diluents are very low in order to minimize the water content of the pharmaceutical composition and that lactose is used in its anhydrous form.”

Applicants respectfully maintain that the Official Action’s basis for this rejection is not applicable to any claim presently in the application.

First, to set forth a *prima facie* case of obviousness over a combination of references, the Official Action must show that there is some suggestion or motivation in the prior art to combine the references in the direction of the claimed invention. *See* M.P.E.P. §2143.01. Nothing in the cited reference suggests specifically using a water content of below about 1%.

Furthermore, the prior art must suggest “the desirability of the claimed invention.” *See* MPEP §2143.01. In other words, to establish a *prima facie* case of obviousness, the Office Action must show a motivation or suggestion in the relevant teachings of the reference. *See In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Applicants respectfully point out that claims presently in the application are directed to specific water content. Thus, to arrive at the “claimed invention,” the Office Action would have to select compositions containing a water content of about below 1% from

the numerous water content that may be used. What is the motivation or suggestion to make such selections of specific water content? Thus, the reference does not suggest or motivate a selection of the specific water content of about below 1%.

On the basis of the foregoing, Applicants respectfully assert that claims 1-21 are not *prima facie* obvious over the cited reference.

Double Patenting rejection

The Office action rejected claims 1-21 under the obviousness-type double patenting doctrine as being unpatentable over claims 1-18 of US Patent No. 6,170,050 (USPN 09/863,986). Claims 1-21 have been provisionally rejected under the obviousness-type double patenting doctrine as unpatentable over co-pending US Application No. 09/450,609. The Office Action states that although the claims are not identical, they are not patentably distinct because the process of preparing the composition comprising the instant compound and having the instant water content renders the instant composition obvious.

Rejection over US Patent No. 6,170,050

Applicants request reconsideration of these rejections. Both the process claims and the composition claims were filed in the same application (see original claims of the '050 patent). The composition claims were cancelled from the '986 application in order to pursue the allowable compound claims. The instant application with the composition claims was filed before the '050 patent issued. Double patenting cannot be justified solely on the ground that the same subject matter of a claim in a second patent application is dominated by the claims in the first patent. See *In re Kaplan*, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986).

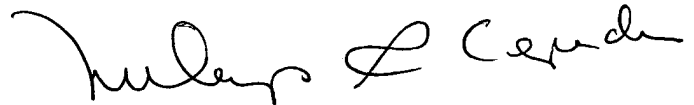
Provisional rejection over US Application No. 09/450,609.

The Office Action has not established a *prima facie* case of obviousness. See above for criteria to establish a *prima facie* case of obviousness. Nothing in the cited reference suggests specifically using water content of below about 1%. Again, to establish a *prima*

facie case of obviousness, the Office Action must show a motivation or suggestion in the teachings of the reference. The cited reference does not suggest or motivate a selection of the specific water content of about below 1%. On the basis of the foregoing, Applicants respectfully assert that claims 1-21 are not *prima facie* obvious over the cited reference.

It is believed that all rejections in the outstanding Office Action had been fully met. Allowance of all pending claims is respectfully requested. The Commissioner is hereby authorized to charge any fee which may be required, or credit any overpayment, to Deposit Account No. 50-3221.

Respectfully submitted,



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